

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Junming Le, Jan Vilcek, Peter Daddona, John Ghrayeb, David M. Knight and
Scott Siegel

Application No.: 10/010,229 Group Art Unit: 1644

Filed: December 7, 2001 Examiner: Phillip Gambel

Confirmation No.: 8474

Title: METHODS OF TREATING NEOPLASTIC DISEASE WITH ANTI-TNF
ANTIBODIES (AS AMENDED)

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| CERTIFICATE OF MAILING OR TRANSMISSION | |
| I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, or is being facsimile transmitted to the United States Patent and Trademark Office on: | |
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SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment
Commissioner for Patents
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Sir:

This Information Disclosure Statement is submitted:

- ☐ under 37 CFR 1.129(a), or
(First/Second submission after Final Rejection)
- ☐ under 37 CFR 1.97(b), or
(Within any one of the following time periods: three months of filing national application (other than a CPA) or date of entry of the national stage in an international application; or before the mailing date of a first office action on the merits in a non-provisional application, including a CPA, or a Request for Continued Examination).
- ☒ under 37 CFR 1.97(c) together with either:
- ☐ a Statement under 37 CFR 1.97(e), as checked below, or
- ☒ a \$180.00 fee under 37 CFR 1.17(p), or
(After the 37 CFR 1.97(b) time period, but before final action or notice of allowance, whichever occurs first)
- ☐ under 37 CFR 1.97(d) together with:
- ☐ a Statement under 37 CFR 1.97(e), as checked below, and
- ☐ a \$180.00 fee under 37 CFR 1.17(p), or
(Filed after final action or notice of allowance, whichever occurs first, but on or before payment of the issue fee)
- ☐ under 37 CFR 1.97(i):
Applicant requests that the IDS and cited reference(s) be placed in the application file.

(Filed after payment of issue fee)

Statement Under 37 CFR 1.97(e)

- ☐ Each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or
- ☐ No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

Statement Under 37 CFR 1.704(d) (Patent Term Adjustment)

Applies to original applications (other than design) filed on or after May 29, 2000

- ☐ Each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.
- ☒ Enclosed herewith is form PTO-1449:
- ☒ Copies of the cited references [AZ11-AV12] are enclosed.
- ☒ Copies of issued U.S. patents and published U.S. applications are not required and are not being provided.
- ☐ Copies of the cited references are enclosed except those entered in prior application, U.S. Application No. [], to which priority under 35 U.S.C. 120 is claimed. [The earlier application contains copies of the cited references.]
- ☐ The listed references were cited in the enclosed International Search Report in a counterpart foreign application.
- ☐ The "concise explanation" requirement (non-English references) for reference(s) [] under 37 CFR 1.98(a)(3) is satisfied by:
- ☐ the explanation provided on the attached sheet.
- ☐ the explanation provided in the Specification.
- ☐ submission of the enclosed International Search Report.
- ☐ submission of the enclosed English-language version of a foreign Search Report and/or foreign Office Action.
- ☐ the enclosed English language abstract.

- ☐ Applicant requests that the following non-published pending applications be considered:
(Affix a label or apply the stamp "Non-Published IDS Reference - Do Not Scan" to the front of each unpublished pending appl'n.)

Examiner's
Initials

____ U.S. Patent Application No. [], by [inventor(s)], filed [], Docket No.: []
____ U.S. Patent Application No. [], by [inventor(s)], filed [], Docket No.: []
____ U.S. Patent Application No. [], by [inventor(s)], filed [], Docket No.: []

Examiner

Date

- ☐ A copy of each above-cited application, including the current claims, is enclosed, except any application filed on or after June 30, 2003, which has been scanned into the PTO's Image File Wrapper (IFW) system and is available to the examiner.
- ☐ A copy of each above-cited application, including the current claims, is enclosed, except those entered in prior application, U.S. Application No. [], to which priority under 35 U.S.C. 120 is claimed.

The Examiner is requested to return a copy of the above list of pending applications indicating which references were considered with the next office communication.

It is requested that the information disclosed herein be made of record in this application.

Method of payment:

- ☒ A check for the fee noted above is enclosed, or the fee has been included in the check with the accompanying Reply. A copy of this Statement is enclosed.
- ☐ Please charge Deposit Account 08-0380 in the amount of \$[]. A copy of this Statement is enclosed.
- ☒ Please charge any deficiency in fees and credit any overpayment to Deposit Account 08-0380.

Respectfully submitted,

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Dated: September 18, 2006

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| PTO-1449 REPRODUCED INFORMATION DISCLOSURE STATEMENT IN AN APPLICATION September 15, 2006 (Use several sheets if necessary) | ATTORNEY DOCKET NO. 0975.1005-014 | | APPLICATION NO. 10/010,229 | |
| | FIRST NAMED INVENTOR Junming Le | | FILING DATE December 7, 2001 | |
| | EXAMINER Phillip Gambel | CONFIRMATION NO. 8474 | GROUP 1644 | |

| U.S. PATENT DOCUMENTS | | | | |
|-------------------------------|-------------|--|--|--|
| EXAM- INER INI- TIAL | REF. NO. | DOCUMENT NUMBER Number-Kind Code (if known) | ISSUE DATE / PUBLICATION DATE MM-DD-YYYY | NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT |
| | AI3 | 5,644,034 | 07-01-1997 | Rathjen <i>et al.</i> |

| OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) | | | | |
|--|------|--|--|--|
| | AZ11 | Cornillie, F. <i>et al.</i> , "Infliximab Induces Potent Anti-Inflammatory and Local Immunomodulatory Activity but no Systemic Immune Suppression in Patients with Crohn's Disease," <i>Aliment. Pharmacol. Ther.</i> , 15:463-473 (2001). | | |
| | AR12 | Wolfe, F. and Michaud, K., "Lymphoma in Rheumatoid Arthritis: The Effect of Methotrexate and Anti-Tumor Necrosis Factor Therapy in 18,572 Patients," <i>Arthritis Rheum.</i> , 50(6):1740-1751 (2004). | | |
| | AS12 | Geysen, H.M. <i>et al.</i> , "A Synthetic Strategy for Epitope Mapping," <i>Peptides: Chemistry and Biology</i> , in <i>Proceedings of the Tenth American Peptide Symposium</i> (Marshall, G.R. Ed.):519-523 (1988). | | |
| | AT12 | Balkwill, F., "Short Survey: Tumor Necrosis Factor or Tumor Promoting Factor?," <i>Cytokine Growth Factor Rev.</i> , 13:135-141 (2002). | | |
| | AU12 | Szlosarek, P.W. and Balkwill, F.R., "Tumour Necrosis Factor α : a Potential Target for the Therapy of Solid Tumours," <i>Lancet</i> , 4:565-573 (2003). | | |
| | AV12 | Brown, S.L. <i>et al.</i> , "Tumor Necrosis Factor Antagonist Therapy and Lymphoma Development," <i>Arthritis Rheum.</i> , 46(12):3151-3158 (2002). | | |